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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,230	06/20/2003	Jack Q. Wilkinson	0325.210US	9796
27123 7590 07/30/2007 MORGAN & FINNEGAN, L.L.P. 3 WORLD FINANCIAL CENTER NEW YORK, NY 10281-2101			EXAMINER COLLINS, CYNTHIA E	
			ART UNIT 1638	PAPER NUMBER
			MAIL DATE 07/30/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/600,230

Applicant(s)

WILKINSON

Examiner

Cynthia Collins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6 and 9-13 is/are pending in the application.
- 4a) Of the above claim(s) 6 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-4, 9 and 13 is/are allowed.
- 6) ☒ Claim(s) 10-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The Pre-Appeal Brief Request for Review filed March 22, 2007 has been considered.

Claims 5, 7-8 and 14-17 are cancelled.

Claims 1-4, 6 and 9-13 are pending.

Claim 6 is withdrawn.

Claims 1-4 and 9-13 are examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

Specification

The abstract of the disclosure remains objected to because it is not descriptive of the elected invention. The title of the invention also remains objected to because it is not descriptive of the elected invention.

Applicants' arguments filed June 9, 2006 have been fully considered but they are not persuasive.

Applicants point out that the specification is amended to make the title and abstract more descriptive of the invention (reply page 8).

The objections are maintained as the amended title and abstract are still not descriptive of the elected invention. It is suggested that the title and abstract be amended to make reference to fungal 3' termination sequences in order to overcome the objection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 10-12 are drawn to the recombinant expression cassette of claim 1 wherein the 3' termination sequence has at least 70%, 80% or 90% sequence identity to a 3' termination sequence of unspecified structure that is native to any unspecified fungal species, and less than 90% identity to a 3' termination sequence of unspecified structure that is native to any unspecified plant species.

With respect to the genus of fungal 3' termination sequences for use in a recombinant expression cassette as set forth in claim 1, the specification describes twenty sequences obtained from *Saccharomyces cerevisiae* (SEQ ID NOS: 1-3, 16-23, 69-76 and 81), four sequences obtained from *Pichia pastoris* (SEQ ID NOS: 24-27) and three sequences obtained from *Aspergillus nidulans* (SEQ ID NOS: 78-80).

With respect to the subgenus of fungal 3' termination sequences for use in a recombinant expression cassette of claim 1 that have at least 70%, 80% or 90% sequence

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identity to a native fungal 3' termination sequence, and less than 90% identity to a native plant 3' termination sequence, the specification is silent with respect to which particular native fungal and plant 3' termination sequences are suitable reference sequences for comparison to the fungal 3' termination sequences for use in a recombinant expression cassette of claim 1; i.e. the specification is silent with respect to the actual percent sequence identities of the disclosed fungal 3' termination sequences (SEQ ID NOS: 1-3, 16-27, 69-76 and 78-81) to any particular native fungal and/or plant 3' termination reference sequences.

Further, the search of the elected sequence of SEQ ID NO:1 detected % sequence identity to fungal sequences obtained from a single species of fungus, *Saccharomyces cerevisiae*, the same species from which SEQ ID NO:1 itself was obtained, and no % identity to any plant sequences.

The Federal Circuit has recently clarified the application of the written description requirement to polynucleotide sequences. The court stated that "A description of a genus of cDNAs may be achieved by means of recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." See *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1569; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

In the instant case Applicant has not described a representative number of species falling within the scope of the claimed subgenus which encompasses fungal 3' termination sequences for use in a recombinant expression cassette as set forth in claim 1 that have at

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least 70%, 80% or 90% sequence identity to a 3' termination sequence of any unspecified structure that is native to any unspecified fungal species, and less than 90% identity to a 3' termination sequence of any unspecified structure that is native to any unspecified plant species, nor the structural features unique to the subgenus.

Allowable Subject Matter

Claims 1-3, 9 and 13 are allowed.

Remarks

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center

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(EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer

Service Representative or access to the automated information system, call 800-786-9199

(IN USA OR CANADA) or 571-272-1000.

Cynthia Collins
Primary Examiner
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CC

Cynthia Collins
7/22/07